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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/772,109	01/26/2001	Allan S. Lau	4099-0003.31	8965

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EXAMINER	
WINKLER, ULRIKE	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/772,109	LAU ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8,11,25,26,29,31-34,37,39 and 40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8,11,25,26,29,31-34,37,39 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed April 21, 2004 in response to the Office Action of October 21, 2003 is acknowledged and has been entered. Claims 1-3, 5-8, 11, 25, 26, 29, 31-34, 37, 39 and 40 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Priority

This application is a CIP of application 09/657881 and the provisional application 60/152854, claims that make reference to CrmA will only be granted the priority to the filing date of the instant application which is January 26, 2001.

Claim Rejections - 35 USC § 102

The rejection of claim 3 under 35 U.S.C. 102(b) as being anticipated by Dixit (U.S. Pat. No. 6,159,712) **is withdrawn** in view of Applicant's amendment to the claim.

Claim Rejections - 35 USC § 103

The rejection of claims 1-8, 11, 12, 25, 26, 29-34 and 37-40 under 35 U.S.C. 103(a) as being unpatentable over Dixit (U.S. Pat. No. 6,159,712), Lau et al. (U.S.Pat. No. 6,159,712) and Suzuki et al. (Derwent Abstract XP-002170158; see IDS Paper No. 13; JP9-163983-A see PTO 892 translation of full patent included) **is maintained** for reasons of record.

Applicant's arguments filed April 21, 2004 have been fully considered but they are not persuasive. In response to Applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to Applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Suzuki et al. does more than just merely teach the prevention of apoptosis in a cell. The teachings of Susuki et al. are directed to the increase in the ability of a cell to produce useful matter (product), such as cytokines, by preventing apoptosis from killing the cell prematurely. The increased cell life translates into an increased production of the product (see paragraph 0021). The reference teaches the use of a cell line to which an apoptosis inhibiting gene has been introduced, such as CrmA. Dixit V.M. teaches the transformation of MCF7 and BJAB cells (human derived cells line) with a vector encoding Crm-A (see examples 3, 4 and 5).

It would have been obvious to one of ordinary skill in the art to utilize the cell line taught by Dixit for the production of useful matter, such as a cytokine, as taught by Suzuki et al. Suzuki et al. also establishes that those cell that contain the apoptosis inhibiting gene produce more protein when compared to cell that do not have the gene insert, the level of protein production doubled at day 7 and tripled at day 14 (see figure 9, Suzuki et al.). In considering the teachings of Dixit and Suzuki et al. one of ordinary skill in the art would have had a high expectation of success in using the cell line of Dixit for the production of useful matter, such as a cytokine, given the teaching of Susuki et al. So the combination of Suzuki et al. and Dixit teaches the use of a CrmA expressing cell for the production of useful matter. Lau et al. teaches a method of producing a cell that is able to overexpress cytokines wherein the cell comprises a vector containing PKR, and the cytokine expression is stimulated by induction using poly I:C and the priming agent PMA. Overexpression of PKR induced overproduction of the cytokines INF-alpha and INF-beta.

> MPEP 2144.06 "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.).

The instant invention is drawn to a composition, a cell line (claim 1) which can produce a cytokine. This cell line expresses a coding sequence for an anti-apoptotic protein, specifically CrmA (claims 2).

For this office action, the preamble of the product-by-process claims were interpreted as "a composition of matter" (which are *products*.). Product-by-process claims are not limited to the

manipulations of the recited steps, only to the structure implied by the steps. M.P.E.P. Section 2113 states that:

> "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

Therefore, it remains the Offices position that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the antiapoptotic protein CrmA with the PKR cell line which both of which are capable of overexpressing cytokines (products). Suzuki et al. suggest the use of combining an apoptosis-suppressive gene including CrmA for the production of cytokines and Lau teaches that the PKR cell line can overexpress a cytokine. One having ordinary skill in the art would have been motivated to include CrmA with the PKR cell line because both can be used for the expression of proteins (cytokines), as taught by Lau and Suzuki et al. Therefore, the instant invention is obvious over of Dixit, Lau et al. and Suzuki et al.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 8/20/04